

**Bard Access Systems, Inc.**

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Salt Lake City, UT 84116  
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**Urgent: CareFusion's Sepp Compound Benzoin Tincture Recall Information**

**Risk Management/Materials Management**

CARDINAL HEALTH D037  
HOSP SUPPLY & SCIENTIFIC PRO  
3080 WEST I-20  
GRAND PRAIRIE, TX 75052

Dear Valued Customer,

This communication is intended to provide you information on a product recall initiated by CareFusion in March 2013. A copy of the CareFusion recall notice is provided as Attachment A. The affected CareFusion product is contained in multiple Bard Access Systems (BAS) manufactured kits, a listing of which is provided as Attachment B. Your facility has been identified as a recipient of these kits over the past 3 years.

The recall on the subject product was initiated by CareFusion due to the labeling on the product could be misleading in relation to the sterility claims. The sterility claim is applicable to the applicator and could mistakenly lead to the conclusion that the drug product solution is sterile as the product labeling states 'Sterility guaranteed unless seal broken' or 'Contents sterile if package is intact'. CareFusion has indicated that there is no patient safety risk associated with these products.

Bard Access Systems has conducted its own evaluation of the issue and agrees with the conclusion that there is no patient safety risk associated based on the intended use of the affected product in BAS kits. As a result, the affected BAS kits with Benzoin Tincture are NOT required to be returned. However, due to a supply disruption the Benzoin Tincture will no longer be included in BAS kits going forward. An alternate skin prep that is contained in the kit will continue to be provided. This action being taken by BAS has been discussed with the FDA (Dallas District) and has received concurrence.

Should you have any questions related to this issue, please contact 1 800 290 1689. We appreciate your cooperation on this matter and sincerely regret any inconvenience this may cause to you or your facility.

Respectfully,

A handwritten signature in black ink, reading 'Ramon Ricart'. The signature is fluid and cursive.

Ramon Ricart  
Vice President, Quality  
Bard Access Systems.

Attachment A – CareFusion Recall Letter  
Attachment B – Affected Product Codes – BAS